

**Remarks**

The Office Action mailed September 19, 2006 has been received and reviewed. No claims having been added, amended, or canceled herein, the pending claims are claims 13-22.

The specification has been amended by inserting a new paragraph at page 24, line 27. The new paragraph is supported by U.S. Patent No. 6,478,842 (Gressel et al.) at, for example, column 1, lines 39-48. The present application explicitly incorporates U.S. Patent No. 6,478,842 (Gressel et al.) by reference at, for example, page 24, lines 25-26 of the present application.

**Pursuant to 37 C.F.R. §1.57(f), Applicants' Representatives hereby state that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter.**

Reconsideration and withdrawal of the rejections are respectfully requested.

**Rejection under 35 U.S.C. §112, First Paragraph**

The Examiner rejected claims 13 and 17 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner asserted that the specification fails to provide adequate written description for the language "theoretical density" in claims 13 and 17. Applicants respectfully disagree. However, in an effort to expedite the prosecution of the present application, the specification has been amended (as discussed herein above) to explicitly recite the language noted by the Examiner, and the rejection has been obviated.

Further, Applicants respectfully disagree with the Examiner's assertion that "applicant cannot pick and choose which features (essential elements) from the incorporated references as forming the basis of his invention" (page 2 of the Office Action mailed September 19, 2006). Applicants have amended the specification in accordance with 37 C.F.R. §1.57 to explicitly recite the claim language noted by the Examiner. Further, the rules clearly state that "information

contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter." M.P.E.P. §2163.06. For at least the reasons discussed herein above, Applicant respectfully submits that the "theoretical density" language recited in claims 13 and 17 is adequately supported by the specification as filed.

In view of the amendments and remarks presented herein, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 13 and 17 under 35 U.S.C. §112, first paragraph.

### **Rejections under 35 U.S.C. §103**

The Examiner rejected claims 13-22 under 35 U.S.C. §103(a) as being unpatentable over Weaver et al. (U.S. Patent No. 6,641,776) in view of either Tomonto (U.S. Patent No. 6,264,687) or Schwartz et al. (U.S. Patent No. 5,443,496). Applicants respectfully traverse the rejections.

"To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. §2143. Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness.

First, Applicants note that the Examiner has not addressed all the claim language in the rejections. The Examiner is reminded that the rules clearly instruct that even if the Examiner alleges that new matter has been added to the claims, "[t]he examiner should still consider the subject matter added to the claim in making rejections based on prior art since the new matter rejection may be overcome by applicant." M.P.E.P. §2163.06(I). However, there is no indication in the body of the rejections under 35 U.S.C. §103(a) in the Office Action mailed September 19, 2006, that the Examiner considered either the claim language added, or the

remarks made, in the Amendment and Response submitted June 20, 2006. Applicants again request that the Examiner consider the claim language added and the remarks made in the Amendment and Response submitted June 20, 2006, which Applicants believe are by themselves sufficient to overcome the rejections of claims 13-22 under 35 U.S.C. §103(a).

Further, Applicants respectfully submit that Weaver et al. in view of Tomonto or Schwartz et al. lack, among other things, a teaching or suggestion of “sintering the composite structure to achieve at least about 95% of the theoretical density of the metal alloy” (e.g., independent claims 13 and 17).

Weaver et al. disclose “a process including the steps of: (a) preparing a mixture composition comprising: i) radiolucent particulate material selected from ceramic materials, metallurgic materials, and combinations thereof and having a particulate size of no more than 40 microns, ii) radiopaque particulate material selected from ceramic materials, metallurgic materials, and combinations thereof and having a particulate size of no more than 40 microns, and (iii) at least one polymeric binder material; (b) injection molding the mixture composition into a preform; (c) optionally removing the binder material from the preform; and (d) sintering the preform” (abstract).

However, Weaver et al. provide no teaching or suggestion of sintering the composite structure to achieve at least about 95% of the theoretical density of the metal alloy as recited in present independent claims 13 and 17. In contrast to a composite having at least about 95% of the theoretical density of the alloy, Weaver et al. teach that the resulting material is “porous” (e.g., column 1, line 52; and column 5, line 56) and necessarily includes pores:

Through adjustment of types of binding agents, added amounts, binder extraction conditions, and sintering conditions, various material properties of the inventive implement can be controlled or set. Examples of such properties include the composition of the surface layer, the pore diameter, and the number of pores. (Column 5, lines 9-14).

Further, the Examiner referred to U.S. Patent No. 5,972,027 (Johnson), which is referred to and incorporated by reference in Weaver et al. (e.g., column 1, lines 52-54 of Weaver et al.). Johnson discloses “stents [that] are formed by subjecting one or more powdered materials in a die cavity to a pressure treatment followed by a heat treatment” (abstract).

Like Weaver et al., Johnson provides no teaching or suggestion of sintering the composite structure to achieve at least about 95% of the theoretical density of the metal alloy as recited in present independent claims 13 and 17. Further Johnson even lacks, among other things, a teaching or suggestion of “at least one polymer binder” and “removing the binder” as recited in each of present independent claims 13 and 17.

Moreover, Johnson state:

The stents of the present invention may be prepared in a range of porosities allowing for the production of stents with differing drug delivery characteristics. The porosity may be between twenty and eighty percent of the total volume and more suitably between forty and sixty percent of the volume. (Column 3, lines 557-61 of Johnson).

Thus, for at least the reason that Johnson discloses stents having *porosity between twenty and eighty percent of the total volume*, Applicants respectfully submit that Johnson teaches away from the presently claimed invention, which includes sintering the composite structure to achieve at least about 95% of the theoretical density of the metal alloy.

Finally, neither Tomonto nor Schwartz et al. provide that which is missing from Weaver et al. (including the incorporation by reference of Johnson).

For at least the reasons discussed herein above, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of unpatentability for claims 13-22 being obvious over Weaver in view of Tomonto or Schwartz et al.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) are respectfully requested.

**Amendment and Response**

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For: MODULATED STENTS AND METHODS OF MAKING THE STENTS

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**Summary**

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants= Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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